



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David A. Edwards and Jeffrey S. Hrkach

Application No.: 09/383,054 Group Art Unit: 1615

Filed: August 25, 1999

Examiner: Amy E. Pulliam

Confirmation No.: 6042

Title: STABLE SPRAY-DRIED PROTEIN FORMULATIONS

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202	
on <u>4/7/03</u>	Signature <u>Rachel Cohen</u>
RACHEL COHEN	
Typed or printed name of person signing certificate	

FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
P.O. Box 2327
Arlington, VA 22202

Sir:

This Information Disclosure Statement is submitted:

 under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

 under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

 under 37 CFR 1.97(c) together with either: a Statement under 37 CFR 1.97(e), as checked below, or a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

 under 37 CFR 1.97(d) together with: a Statement under 37 CFR 1.97(e), as checked below, and a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

 under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

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Statement Under 37 CFR 1.97(e)

- Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

Copies of the cited references are enclosed.

Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]

The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:

the explanation provided on the attached sheet.

the explanation provided in the Specification.

submission of the enclosed International Search Report.

submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

the enclosed English language abstract.

[] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

[] A copy of each above-cited application, including the current claims, is enclosed.

[] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Anne I. Craig
Anne I. Craig
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Concord, MA 01742-9133

Dated: 4/4/03

PTO-1449 REPRODUCED

FOURTH SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

APR 09 2003

April 1, 2003

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2685.1003-001APPLICATION NO.
09/383,054

APPLICANT

David A. Edwards, *et al.*

FILING DATE

August 25, 1999

CONFIRMATION NO.

6042

GROUP
1615

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AJ3	2,470,296	05/17/49	Fields
	AK3	2,533,065	12/05/50	Taplin <i>et al.</i>
	AA4	2,992,645	07/18/61	Fowler
	AB4	3,781,230	12/25/73	Vassiliades <i>et al.</i>
	AC4	3,957,965	05/18/76	Harley <i>et al.</i>
	AD4	4,009,280	02/22/77	Macarthur, <i>et al.</i>
	AE4	4,089,800	05/16/78	Temple
	AF4	4,161,516	07/17/79	Bell
	AG4	4,173,488	11/06/79	Vassiliades, <i>et al.</i>
	AH4	4,272,398	06/09/81	Jaffe
	AI4	4,352,883	10/05/82	Lim
	AJ4	4,391,909	07/05/83	Lim
	AK4	4,466,442	08/21/84	Hilmann, <i>et al.</i>
	AA5	4,480,041	10/30/84	Myles, <i>et al.</i>
	AB5	4,524,769	06/25/85	Wetterlin
	AC5	4,572,203	02/25/86	Feinstein
	AD5	4,590,206	05/20/86	Forrester <i>et al.</i>
	AE5	4,615,697	10/07/86	Robinson
	AF5	4,679,555	07/14/87	Sackner
	AG5	4,741,872	05/03/88	De Luca, <i>et al.</i>
	AH5	4,743,545	05/10/88	Torobin
	AI5	4,774,958	10/04/88	Feinstein
	AJ5	4,789,550	12/06/88	Hommel, <i>et al.</i>
	AK5	4,818,542	04/04/89	De Luca, <i>et al.</i>
	AA6	4,847,091	07/11/89	Illum

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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2685.1003-001	APPLICATION NO. 09/383,054
FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION		APPLICANT David A. Edwards, <i>et al.</i>	
APR 09 2003 SEARCHED SERIALIZED INDEXED APR 11 2003 TECH CENTER 1600 RECEIVED Use several sheets if necessary)		FILING DATE August 25, 1999	CONFIRMATION NO. 6042
			GROUP 1615

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AB6	4,855,144	08/08/89	Leong, <i>et al.</i>
	AC6	4,857,311	08/15/89	Domb, <i>et al.</i>
	AD6	4,861,627	08/29/89	Mathiowitz, <i>et al.</i>
	AE6	4,865,789	09/12/89	Castro, <i>et al.</i>
	AF6	4,904,479	02/27/90	Illum
	AG6	4,917,119	04/17/90	Potter, <i>et al.</i>
	AH6	4,963,297	10/16/90	Madden
	AI6	4,976,968	12/11/90	Steiner
	AJ6	4,994,281	02/19/91	Muranishi, <i>et al.</i>
	AK6	5,033,463	07/23/91	Cocozza
	AA7	5,064,650	11/12/91	Lew
	AB7	5,069,936	12/03/91	Yen
	AC7	5,075,109	12/24/91	Tice <i>et al.</i>
	AD7	5,100,669	03/31/92	Hyon <i>et al.</i>
	AE7	5,123,414	06/23/92	Unger
	AF7	5,145,684	09/08/92	Liversidge <i>et al.</i>
	AG7	5,160,745	11/03/92	De Luca <i>et al.</i>
	AH7	5,169,871	12/08/92	Hughes <i>et al.</i>
	AI7	5,174,988	12/29/92	Mautone <i>et al.</i>
	AJ7	5,195,520	03/23/93	Schlieff, <i>et al.</i>
	AK7	5,204,108	04/20/93	Illum
	AA8	5,204,113	04/20/93	Hartley, <i>et al.</i>
	AB8	5,260,306	11/09/93	Boardman <i>et al.</i>
	AC8	5,271,961	12/21/93	Mathiowitz, <i>et al.</i>
	AD8	5,306,483	04/26/94	Mautone

EXAMINER	DATE CONSIDERED
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AE8	5,327,883	07/12/94	Williams, <i>et al.</i>
	AF8	5,334,381	08/02/94	Unger
	AG8	5,340,587	08/23/94	Milhalko <i>et al.</i>
	AH8	5,352,435	10/04/94	Unger
	AI8	5,384,133	01/24/95	Boyes <i>et al.</i>
	AJ8	5,393,524	02/28/95	Quay
	AK8	5,407,609	04/18/95	Tice, <i>et al.</i>
	AA9	5,456,917	10/10/95	Wise <i>et al.</i>
	AB9	5,466,841	11/14/98	Horrobin, <i>et al.</i>
	AC9	5,482,946	01/09/96	Clark, <i>et al.</i>
	AD9	5,518,709	05/21/96	Sutton, <i>et al.</i>
	AE9	5,518,998	05/21/96	Bäckström, <i>et al.</i>
	AF9	5,551,489	09/03/96	Trofast, <i>et al.</i>
	AG9	5,580,575	12/03/96	Unger <i>et al.</i>
	AH9	5,607,695	03/04/97	Ek <i>et al.</i>
	AI9	5,607,915	03/04/97	Patton
	AJ9	5,612,053	03/18/97	Baichwal <i>et al.</i>
	AK9	5,614,216	03/25/97	Janoff
	AA10	5,654,007	08/05/97	Johnson
	AB10	5,690,954	11/25/97	Illum
	AC10	5,698,721	12/16/97	Heath
	AD10	5,707,644	01/13/98	Illum
	AE10	5,709,884	01/20/98	Trofast, <i>et al.</i>
	AF10	5,780,014	07/14/98	Eljamal
	AG10	5,795,594	08/18/98	York, <i>et al.</i>

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APR 09 2003 RECEIVED U.S. PATENT AND TRADEMARK OFFICE Use several sheets if necessary)		FILING DATE August 25, 1999	CONFIRMATION NO. 6042
		GROUP 1615	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
	AH10	5,804,212	09/08/98	Illum
	AI10	5,814,607	09/29/98	Patton
	AJ10	5,830,853	11/03/98	Bäckström, <i>et al.</i>
	AK10	5,851,453	12/22/98	Hanna, <i>et al.</i>
	AA11	5,874,063	02/23/99	Briggner <i>et al.</i>
	AB11	5,885,613	03/23/99	Holland <i>et al.</i>
	AC11	5,902,802	05/11/99	Heath
	AD11	5,922,354	07/13/99	Johnson
	AE11	5,928,469	07/27/99	Franks <i>et al.</i>
	AF11	5,993,783	11/30/99	Eljamal
	AG11	6,019,968	02/01/00	Platz
	AH11	6,051,256	04/18/00	Platz
	AI11	6,063,138	08/15/00	Hanna <i>et al.</i>
	AJ11	6,080,721	06/27/00	Patton
	AK11	6,103,270	08/15/00	Johnson
	AA12	6,123,936	09/26/00	Platz
	AB12	6,136,346	10/24/00	Eljamal
	AC12	6,153,224	11/28/02	Staniforth
	AD12	6,187,330 B1	02/13/01	Wang <i>et al.</i>
	AE12	6,187,344 B1	02/13/01	Eljamal
	AF12	6,231,851 B1	05/15/01	Platz
	AG12	6,258,341 B1	07/10/01	Foster
	AH12	6,303,582 B1	10/16/01	Eljamal
	AI12	6,309,671 B1	10/30/01	Foster
	AJ12	6,315,983 B1	11/13/01	Eistetter

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EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 2685.1003-001	APPLICATION NO. 09/383,054
FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION	APPLICANT David A. Edwards, <i>et al.</i>	
APR 09 2003 SJC PAI (See several sheets if necessary)	FILING DATE August 25, 1999	CONFIRMATION NO. 6042
		GROUP 1615

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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2685.1003-001	APPLICATION NO. 09/383,054
FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION		APPLICANT David A. Edwards, <i>et al.</i>	
APR 09 2003 SAC use several sheets if necessary)		FILING DATE August 25, 1999	CONFIRMATION NO. 6042
		GROUP 1615	

FOREIGN PATENT DOCUMENTS						
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO
AQ2	WO 80/02365	13/11/80	PCT			
AL3	WO 86/06959	04/12/86	PCT			
AM3	WO 88/04556	30/06/88	PCT			
AN3	WO 88/09163	01/12/88	PCT			
AO3	WO 91/04732	18/04/91	PCT			
AP3	WO 91/06286	16/05/91	PCT			
AQ3	WO 91/06287	16/05/91	PCT			
AL4	WO 91/12823	05/09/91	PCT			
AM4	This reference number intentionally left blank					
AN4	WO 92/18164	29/10/92	PCT			
AO4	WO 92/21382	10/12/92	PCT			
AP4	WO 93/25221	23/12/93	PCT			
AQ4	WO 94/04133	03/03/94	PCT			
AL5	WO 94/07514	14/04/94	PCT			
AM5	WO 94/08627	28/04/94	PCT			
AN5	WO 94/16739	04/08/94	PCT			
AO5	WO 95/00127	05/01/95	PCT			
AP5	WO 95/07072	16/03/95	PCT			
AQ5	WO 95/24183	14/09/95	PCT			
AL6	WO 95/31479	23/11/95	PCT (Platz)			
AM6	WO 95/35097	28/12/95	PCT			
AN6	WO 96/09814	04/04/96	PCT			
AO6	This reference number intentionally left blank					
AP6	WO 96/23485	08/08/96	PCT			

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EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 2685.1003-001	APPLICATION NO. 09/383,054	
FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION		APPLICANT David A. Edwards, <i>et al.</i>		
April 1, 2003 (Use several sheets if necessary)		FILING DATE August 25, 1999	CONFIRMATION NO. 6042	GROUP 1615

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FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO
AQ6	WO 96/32096	17/10/96	PCT (Eljamal)			
AL7	WO 96/32116	17/10/96	PCT (Eljamal)			
AM7	WO 96/32149	17/10/96	PCT (Platz)			
AN7	WO 96/40963	19/12/96	PCT			
AO7	WO 96/41873	27/12/96	PCT			
AP7	WO 97/03649	06/02/97	PCT			
AQ7	WO 97/36574	09/10/97	PCT			
AL8	This reference number intentionally left blank					
AM8	WO 98/16205	23/04/98	PCT (Foster)			
AN8	WO 98/29096	09/07/98	PCT (Gordon)			
AO8	WO 98/29098	09/07/98	PCT (Gordon)			
AP8	WO 98/29140	09/07/98	PCT (Gordon)			
AQ8	WO 98/29141	09/07/98	PCT (Gordon)			
AL9	WO 98/51278	19/11/98	PCT			
AM9	WO 99/16419	08/04/99	PCT			
AN9	WO 99/16420	08/04/99	PCT			
AO9	WO 99/16421	08/04/99	PCT			
AP9	WO 99/16422	08/04/99	PCT			
AQ9	WO 99/66903	29/12/99	PCT			
AL10	WO 00/15262	23/03/00	PCT (Clark)			
AM10	WO 00/21594	20/04/00	PCT (Clark)			
AN10	WO 00/33811	15/06/00	PCT			
AO10	WO 01/00312 A1	04/01/01	PCT (Bennett)			
AP10	WO 01/13891 A3	01/03/01	PCT			

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FOURTH SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

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April 1, 2003

ATTORNEY DOCKET NO.
2685.1003-001APPLICATION NO.
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David A. Edwards, *et al.*FILING DATE
August 25, 1999CONFIRMATION NO.
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FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO
AQ10	WO 01/32144 A1	10/05/01	PCT (Lechuga-Ballesteros)			
AL11	WO 02/09669 A3	07/02/00	PCT (Snyder)			
AM11	WO 02/11695 A3	14/02/02	PCT (Stevenson)			
AN11	WO 02/054868 A2	18/07/02	PCT (Weickert)			
AO11	WO 02/055101 A2	18/07/02	PCT (Hastedt)			
AP11	WO 02/087542 A1	07/11/02	PCT (Bot)			
AQ11	EP 0 072 046 A1	16/02/03	EPO			
AL12	EP 0 213 303 B1	04/09/91	EPO			
AM12	EP 0 257 915 A1	02/03/88	EPO			
AN12	EP 0 257 956 B1	20/05/92	EPO			
AO12	EP 0 324 938 A1	26/07/89	EPO			
AP12	EP 0 335 133 A2	04/10/89	EPO			
AQ12	EP 0 458 745 A1	14/05/91	EPO			
AL13	EP 0 510 731 A1	28/10/92	EPO			
AM13	EP 0 634 166 A1	18/01/95	EPO			
AN13	EP 0 656 206 A1	07/06/95	EPO			
AO13	1 288 583	17/11/69	GB			
AP13	1,300,009	05/05/92	Canada			
AQ13	1,302,258	02/06/92	Canada			
AL14	2,058,428	05/09/00	Canada			
AM14	2,085,884	30/12/91	Canada			
AN14	2,111,002	22/08/00	Canada			
AO14	2,126,244	26/09/00	Canada			
AP14	2,166,108	05/01/95	Canada			
AQ14	2,170,394	02/03/95	Canada			

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PTO-1449 REPRODUCED	ATTORNEY DOCKET NO. 2685.1003-001	APPLICATION NO. 09/383,054
FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION April 1, 2003 (use several sheets if necessary)	APPLICANT David A. Edwards, <i>et al.</i>	
	FILING DATE August 25, 1999	CONFIRMATION NO. 6042
		GROUP 1615

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

ARS	Adjei, A., and Garren, J., "Pulmonary Delivery of Peptide Drugs: Effect of Particle Size on Bioavailability of Leuprolide Acetate in Healthy Male Volunteers," <i>Pharm. Res.</i> , 7(6):565-569 (1990).
AS5	Allen, T.M., <i>et al.</i> , "Subcutaneous Administration of Liposomes: A Comparison with the Intravenous and Intraperitoneal Routes of Injection," <i>Biochem. et Biophys. Acta.</i> 1150:9-16 (1993).
AT5	Altshuler, B., <i>et al.</i> , "Aerosol Deposition in the Human Respiratory Tract," <i>Am. Med. Assoc. Arch. of Indust. Health</i> 15:293-303 (1957).
AU5	Anderson, P.J., <i>et al.</i> , "Effect of Cystic Fibrosis on Inhaled Aerosol Boluses," <i>Am. Rev. Respir. Dis.</i> , 140:1317-1324 (1989).
AV5	Anderson, M., <i>et al.</i> , "Human Deposition and Clearance of 6- μ m Particles Inhaled with an Extremely Low Flow Rate," <i>Exp. Lung Res.</i> , 21:187-195 (1995).
AW5	Barrera, D.A., <i>et al.</i> , "Synthesis and RGD Peptide Modification of a New Biodegradable Copolymer: Poly(lactic acid-co-lysine)," <i>J. Am. Chem. Soc.</i> , 115:11010-11011 (1993).
AX5	Beck, L.R., <i>et al.</i> , "A New Long-Acting Injectable Microcapsule System for the Administration of Progesterone," <i>Fertility and Sterility</i> , 31(5):545-551 (1979).
AY5	Benita, S., <i>et al.</i> , "Characterization of Drug-loaded Poly(<i>d,l</i> -lactide) Microspheres," <i>J. of Pharm. Sci.</i> 73(12):1721-1724 (1984).
AZ5	Blackett, P.M., and G. Buckton, "A Microcalorimetric Investigation of the Interaction of Surfactants with Crystalline and Partially Crystalline Salbutamol Sulphate in a Model Inhalation Aerosol System," <i>Pharmaceutical Research</i> , 12(11):1689-1693 (1995).
AR6	Brain, J.D., "Physiology and Pathophysiology of Pulmonary Macrophages". In <i>The Reticuloendothelial System</i> , Reichard and Filkins, eds. (Plenum Press, New York), pp. 315-327 (1985).
AS6	Brown, A.R., <i>et al.</i> , "Propellant-Driven Aerosols of Functional Proteins as Potential Therapeutic Agents in the Respiratory Tract," <i>Immunopharmacology</i> , 28:241-257 (1994).
AT6	Byron, P.R., "Determinants of Drug and Polypeptide Bioavailability from Aerosols Delivered to the Lung," <i>Adv. Drug Del. Rev.</i> , 5:107-132 (1990).
AU6	Carroll, B.A., <i>et al.</i> , "Gelatin Encapsulated Nitrogen Microbubbles as Ultrasonic Contrast Agents," <i>Investigative Radiology</i> , 15:260-266 (1980).

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.
2685.1003-001APPLICATION NO.
09/383,054FOURTH SUPPLEMENTAL
INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

APPLICANT

David A. Edwards, *et al.*

April 1, 2003

FILING DATE

August 25, 1999

CONFIRMATION NO.
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April 1, 2003 (use several sheets if necessary)	FILING DATE August 25, 1999	CONFIRMATION NO. 6042
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David A. Edwards, *et al.*FILING DATE
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APR 09 2003 C58 PATENT & TRADEMARK OFFICE Use several sheets if necessary	APPLICANT	David A. Edwards, <i>et al.</i>
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